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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,611	05/04/2001	Andy Swenson	10265.96.1	9485

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	5

DATE MAILED: 08/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/849,611	SWENSON ET AL.	
	Examiner	Art Unit	
	Susan Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *16-20 and 39-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 21-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicant's Information Disclosure Statement filed 06/22/01, Declaration and Fee filed 02/26/02.

Election/Restrictions

During a telephone conversation with Robyn N. Phillips on 08/20/02 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-15, and 21-38. Affirmation of this election must be made by applicant in replying to this Office action. Claims 16-20, and 39-43 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15, and 21-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is indefinite in the use of the phrase "substantially free of wheat protein, barley protein, oat protein and rye protein". It is unclear because the metes and bounds of the patent protection desired are unascertainable. While applicant's specification disclosed "Maltrin® maltodextrins are preferred because they reportedly contain no proteins from wheat, barley, oats or rye", the specification does not disclose any percent or amount of wheat protein, barley protein, oat protein or rye protein that is "substantially free" from maltodextrin. Further clarification is suggested.

Claim 21 is rejected because it is unclear whether the "bioactive substance" in component (c) is an additional substance to the bioactive substance recites in line 2 of claim 21. Further clarification is requested.

Claim 33 is rejected because it is unclear whether the "glucosamine-based substance" in component (c) is an additional substance to the glucosamine-base substance recites in line 2 of claim 33. Further clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, and 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Grillo et al. US 5,470,581.

Grillo teaches dry powder film coating composition for pharmaceutical tablet, the coating comprising from 4-90% cellulosic polymer, and from 5-78.5% maltodextrin (column 2, and abstract). The weight ratio of cellulosic polymer to maltodextrin is 3:7 (id).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grillo et al.

Grillo is relied upon for the reason stated above. In the case that applicant can overcome the above 102(b) rejection, it is the examiner's position that it would have been obvious for one of ordinary skill in the art to modify Grillo's composition with the expectation of at least similar result, because Grillo obtains the same formulation desire by the applicant, i.e., mixture of cellulosic polymer and maltodextrin as dry powder edible film coating composition for use in pharmaceutical tablet (abstract).

Claims 21-23, and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grillo et al., and Baichwal et al. US 5,128,143.

Grillo is relied upon for the reason stated above. Grillo does not teach the sustained release time period.

Baichwal teaches sustained release excipient and tablet formulation comprising active medicament; polysaccharide gum, *e.g.*, hydroxypropylmethyl cellulose, hydroxypropyl cellulose, or carboxymethyl cellulose; and diluent, *e.g.*, microcrystalline cellulose, dextrose, or mixtures thereof (columns 6-8). The dissolution time for the active medication is within about 3.5-5 hours (column 9, lines 43-60). Hence, it would have been prima facie obvious for one of ordinary skill in the art to modify Grillo's coating composition for pharmaceutical tablet in view of the teaching of Baichwal, because the cited references teach the advantageous results in the use of cellulose and dextrose or maltodextrin. The expected result would be a useful excipient composition, which can be blended with a wide variety of active medicaments for sustained/controlled release tablet dosage form.

Claims 2-6, 33, and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grillo et al., and Lord et al. US 6,417,227.

Grillo is relied upon for the reasons stated above. Grillo teaches the use of medicament, but silent as to the teaching of the specific medicament being claimed.

Lord teaches delayed release oral dosage form comprising cetyl myristoleate, and one or more agents selected from glucosamine sulfate, chondrointin sulfate, and methylsulfonylmethane (columns 2-3). The oral dosage form can be a coated capsule or tablet to provide release in the small intestine instead of the stomach (columns 7-9).

Thus, it would have been prima facie obvious for one of ordinary skill in the art to prepare Lord's formulation using the coating excipient in view of the teaching of Grillo, because the cited references teach the advantageous results of cellulose and polysaccharide useful for coating oral dosage form.

Claims 14, 15, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grillo et al., in view of Lord et al., and Grain processing Corporation.

Grillo and Lord are relied upon for the reasons stated above. The references are silent as to the teaching of the claimed maltodextrin.

Grain processing corporation teaches maltodextrin, such as Maltrin® having no protein, fat, or fiber, which is commonly used in consumer products as dry mixes (pages 1-2). Hence, it would have been obvious for one of ordinary skill in this art to modify Grillo's maltodextrin using Maltrin® in view of the teaching of Grain processing Corporation. The reason for this modification is to obtain an excellent dry powder edible film coating composition for use in pharmaceutical, food and confectionery forms.

Claims 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grillo et al., and Baichwal et al., and Lord et al.

Regarding to claims 24-28, Grillo and Baichwal do not teach the specific active agent.

Lord teaches delayed release oral dosage form comprising cetyl myristoleate, and one or more agents selected from glucosamine sulfate, chondrointin sulfate, and

methylsulfonylmethane (columns 2-3). The oral dosage form can be a coated capsule or tablet to provide release in the small intestine instead of the stomach (columns 7-9). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify the compositions of Grillo and Baichwal with the active agents in view of Lord's teaching to obtain the claimed invention, since the cited references teach the advantageous results of cellulose and polysaccharide useful for coating oral dosage form.

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grillo et al., and Bertini et al. US 6,069,172.

Grillo is relied upon for the reasons stated above. Grillo does not teach the claimed cellulose polymer.

Bertini teaches excipient composition for controlled release oral dosage form comprising maltodextrins and powdered cellulose. Although Bertini does not teach the polymerization degree range of cellulose, it is the examiner's position that, it would have been obvious for one of ordinary skill in this art to, by routine experimentation determine a suitable cellulose powder to obtain a desirable dry powder coating composition.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Murad and Petrus are cited as of interest for the teaching of sustained release composition containing glucosamine.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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